

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TENNESSEE  
KNOXVILLE DIVISION

STATE OF TENNESSEE, STATE OF ALA- )  
BAMA, STATE OF ARKANSAS, STATE OF )  
GEORGIA, STATE OF IDAHO, STATE OF )  
INDIANA, STATE OF IOWA, STATE OF )  
LOUISIANA, STATE OF MONTANA, )  
STATE OF NEBRASKA, STATE OF )  
NORTH DAKOTA, STATE OF OHIO, )  
STATE OF SOUTH CAROLINA, STATE OF )  
SOUTH DAKOTA, STATE OF WEST VIR- )  
GINIA, )

)  
*Plaintiffs,* )  
v. )  
)

)  
U.S. DEPARTMENT OF HEALTH AND )  
HUMAN SERVICES; ROBERT F. KEN- )  
NEDY, JR., in his official capacity as Secretary )  
of the U.S. Department of Health and Human )  
Services; and U.S. DEPARTMENT OF )  
HEALTH AND HUMAN SERVICES OF- )  
FICE OF CIVIL RIGHTS, )

)  
*Defendants.* )  
)  
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)  
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Civil Action No. 3:25-cv-00025  
Judge Katherine A. Crytzer  
Magistrate Judge Jill E. McCook

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**PLAINTIFFS' COMBINED RESPONSE TO DEFENDANTS' MOTION TO  
DISMISS AND REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY  
JUDGMENT AND PRELIMINARY RELIEF**

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## INTRODUCTION

HHS does not defend the Final Rule on the merits. Instead, it claims Plaintiff States have not demonstrated standing and, in any event, that universal vacatur is inappropriate. Both arguments fail.

It is basic APA law that parties subject to a challenged regulation generally have an “easy” case for standing because the imposition of a regulatory burden itself causes injury. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). The Final Rule directly regulates Plaintiff States: Each is a sovereign that operates HIPAA-covered entities (with a new duty to validate attestations) as well as law-enforcement agencies that investigate public-health violations (with a new duty to make attestations). So Plaintiff States plainly have standing to challenge the new rule-made obligations they must follow. On top of Plaintiff States’ regulatory harms, their new compliance obligations require time, resources, and personnel and further slow investigations meant to promote their sovereign interest in “safeguard[ing] ‘[their] domain’ and [their citizens’] ‘health, comfort and welfare.’” *Kentucky v. Biden*, 23 F.4th 585, 596 (6th Cir. 2022) (citations omitted). HHS’s claim (at 12) that Plaintiff States offer “no evidence” of these compliance- and sovereignty-based harms ignores fifteen declarations detailing Plaintiff States’ efforts to navigate the Final Rule’s new regime, and the States have secured more.

HHS’s silence on the Final Rule’s substance is fitting. As Plaintiff States explained, HHS lacks statutory power to impose the Final Rule’s bespoke reproductive healthcare-privacy regime. States’ Br. 12-20. Nor does the Final Rule’s scheme clear the APA’s bar for reasoned decision-making: It requires non-lawyers to resolve difficult, abstract legal questions before disclosing information under threat of criminal penalty while granting investigative targets near-veto power over providing records of their potential wrongdoing. *Id.* at 20-22. HHS contests neither merits claim, forfeiting both. *Adkins v. Marathon Petrol. Co., LP*, 105 F.4th 841, 854 (6th Cir. 2024). Plaintiff States are thus “likely to succeed.” *See Tennessee v. U.S. Dep’t of Educ.*, 104 F.4th 577, 607 (6th Cir. 2024). Though that unlocks a right to preliminary relief, States’ Br. 23-25, the final legal issues here do not turn on anything further.

To promote clarity in state programs and investigations, this Court should proceed to final judgment, hold that the Final Rule is “unlawful,” and set it aside. 5 U.S.C. § 706(2)(A), (C).

That means vacatur of the Final Rule. Vacatur is “the default” remedy when agencies act unlawfully. *Kentucky v. EPA*, 123 F.4th 447, 473 (6th Cir. 2024); *accord Corner Post, Inc. v. Bd. of Governors of Fed. Rsv. Sys.*, 603 U.S. 799, 831 (2024) (Kavanaugh, J., concurring) (collecting cases). This is not one of the “rare” instances when an alternative remedy suffices. *Kentucky v. EPA*, 123 F.4th at 473. If anything, the way the Final Rule compels third parties to gum up state investigations counsels a clean remedy like vacatur rather than a party-specific injunction with complex implementation concerns. Nor can severance salvage some kernel of the Final Rule given HHS’s pervasive lack of statutory authority. *See Tennessee v. Cardona*, No. 24-5588, 2024 WL 3453880, at \*4 (6th Cir. July 17, 2024).

In sum, Plaintiff States have standing, the Final Rule is unlawful, and entry of relief is warranted to stop the States’ ongoing harms. The Court should therefore enter summary judgment for Plaintiff States, or at a minimum grant preliminary relief that protects Plaintiff States from the Final Rule’s unlawful mandates.

## ARGUMENT

### I. Plaintiff States have standing.

Because they are directly regulated by the Final Rule—in their capacities as HIPAA-covered entities and investigators requesting HIPAA-protected information—Plaintiff States’ standing is “self-evident.” *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d 501, 508 (W.D. Ky. 2024) (quoting *Tennessee Republican Party v. SEC*, 863 F.3d 507, 517 (6th Cir. 2017)). Plaintiff States’ complaint demonstrates why, alleging standing to a degree that amply satisfies Rule 12’s requirements (which HHS agrees govern its motion to dismiss, *see* HHS Br. 7). The States’ accompanying declarations, which detail the Final Rule’s disruptive and costly impacts, crystallize that the Final Rule causes concrete harms with evidence sufficient to support entry of judgment or preliminary relief.<sup>1</sup> And the States provide more proof now.<sup>2</sup> Further, a remedy against the Final Rule would redress the States’ injuries, which flow directly from the rule. HHS’s counters on standing are misplaced in this APA context.

#### A. Plaintiff States adequately allege their standing as directly regulated entities.

1. Typically, under the APA, standing is “easy to establish” when a party seeks to challenge a rule that directly regulates it. *All for Hippocratic Med.*, 602 U.S. at 382. That axiom governs here, where

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<sup>1</sup> Groover Decl., Dkt. #26-1; Zeigler Decl., Dkt. #26-2; Kreutz Decl., Dkt. #26-3; Johnson Decl., Dkt. #26-5; Spahr Decl., Dkt. #26-6; Traxler Decl., Dkt. #26-7; Targia Decl., Dkt. #26-8; Klenski Decl., Dkt. #26-9; Joiner Decl., Dkt. #26-10; Dietz Decl., Dkt. #26-11; Menefee Decl., Dkt. #26-12; Azar Decl., Dkt. #26-13; Stover Decl., Dkt. #26-14; Osborne Decl., Dkt. #26-15; Karrasch Decl., Dkt. #27.

<sup>2</sup> Decl. of Charles Hardin (Exhibit Q); Decl. of Tammera Harrelson (Exhibit R); Decl. of Lisa Davies (Exhibit S); Decl. of Andrew Pack (Exhibit T); Supp. Decl. of Katherine Zeigler (Exhibit U); Decl. of Kelsey McKnight (Exhibit V). Plaintiffs regularly file, and courts routinely approve, supplemental declarations in response to particular opposition points or in support of preliminary relief. *See, e.g., Tennessee v. Cardona*, No. 2:24-cv-72, Dkt. #94 (E.D. Ky. June 7, 2024) (allowing leave to file supplemental declaration rebutting lack-of-harm argument); *Bingham v. Root*, No. 6:22-cv-00094, Dkt. #15-1 (E.D. Ky. July 11, 2022) (supplemental declaration rebutting claim that plaintiff had not established a preliminary injunction factor); *MxPx Global Enters. v. Tooth & Nail Record*, No. 3:01-cv-00377, Dkt. # 31 (M.D. Tenn. May 30, 2001) (granting plaintiffs leave to file reply and additional declarations in support of their preliminary injunction motion); *cf. LR7.1(a)*. Though Plaintiff States have explained why relief is warranted even absent these declarations, they alternatively seek leave to file the supplemental declarations appended here.

the Plaintiff States have adequately alleged that the Final Rule directly regulates and harms them.

To start, “[t]he imposition of a regulatory burden itself causes injury.” *Tennessee v. EEOC*, 129 F.4th 452, 458 (8th Cir. 2025); *see also Tex. Med. Ass’n v. HHS*, 110 F.4th 762, 773 (5th Cir. 2024). So, “regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements.” *All. for Hippocratic Med.*, 602 U.S. at 382. For example, the Supreme Court held in *West Virginia v. EPA* that the “plaintiff States were injured by an EPA regulation” because they were ““the object of its requirement that they more stringently regulate power plant emissions within their borders.” *Tennessee v. EEOC*, 129 F.4th at 458 (quoting 597 U.S. 697, 719 (2022)). The Court “deemed it unnecessary” to further “consider whether the requirement caused any specific economic harms.” *Id.* Indeed, setting aside “myriad other” potential injuries, “including compliance costs and economic harms,” allegations that a State is the object of an agency action that compels or prohibits some activity establish standing. *See Carmen v. Yellen*, 112 F.4th 386, 407-08 (6th Cir. 2014). “No additional proof is necessary when a rule purports to impose legal obligations directly on a state plaintiff.” *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 507.

The multiple bases for this well-worn principle are broadly accepted. *First*, “[i]n our federal system, the National Government possesses only limited powers; the States and the people retain the remainder.” *Bond v. United States*, 572 U.S. 844, 854 (2014). States thus have “their *own* interests” as sovereigns in self-government to “safeguard ‘[their] domain’ and [their citizens’] ‘health, comfort and welfare.’” *Kentucky v. Biden*, 23 F.4th at 596 (citations omitted). So they have a “concrete interest” in “avoiding regulatory obligations above and beyond those that can be statutorily imposed upon them.” *Iowa League of Cities v. EPA*, 711 F.3d 844, 871 (8th Cir. 2013). *Second*, “complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs” given the federal government’s sovereign immunity. *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring in part); *see Kentucky v. Biden*, 57 F.4th 545, 555-56 (6th Cir. 2023). The

Final Rule acknowledges it comes with costs. 89 Fed. Reg. at 33,054-56. Those compliance costs “are a recognized harm” for Article III purposes. *Kentucky v. Yellen*, 54 F.4th 325, 342 (6th Cir. 2022).

Thus, the Supreme Court, the Sixth Circuit, and other courts of appeals have recognized that standing generally is “self-evident” for the object of a regulation.<sup>3</sup> States’ standing to challenge direct federal regulation is so well established that courts have been unable to cite “a single precedent holding that ‘states lack standing to challenge a rule that operates on States qua States.’” *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 507. A case cutting the other way—a district-court decision in *Tennessee v. EEOC*—was unanimously reversed in straightforward fashion. 129 F.4th at 458.

2. HHS does not dispute the obvious: the Final Rule directly regulates Plaintiff States. As health-plan administrators and healthcare providers, States must disclose HIPAA-protected information consistent with the Final Rule. As law enforcement entities, States must jump through new Final-Rule-created hoops to obtain HIPAA-protected information for public health investigations.

Plaintiff States plausibly alleged the bases for those conclusions. Each plaintiff is a “sovereign,” Compl. ¶¶ 3-17, that operates HIPAA-covered entities, *id.* ¶¶ 113-15, and conducts investigations promoting health and welfare that often rely on medical records obtained from HIPAA-covered entities, *id.* ¶¶ 91-112. Plaintiff States also allege that the Final Rule imposes new burdens on both HIPAA-covered entities and investigators. For example, HIPAA-covered entities now must undertake a complex legal assessment to evaluate whether requested records will be used “[t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.” *Id.* ¶¶ 67-71. For investigators, the Final Rule

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<sup>3</sup> See, e.g., *West Virginia*, 597 U.S. at 719; *Tennessee v. EEOC*, 129 F.4th at 458; *Tex. Med. Ass’n*, 110 F.4th at 773; *Carmen*, 112 F.4th at 407-08; *New Mexico v. U.S. Dep’t of Interior*, 854 F.3d 1207, 1218 (10th Cir. 2017); *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011); *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002); *Cotovsky-Kaplan Physical Therapy Assocs., Ltd. v. United States*, 507 F.2d 1363, 1366 (7th Cir. 1975).

imposes a new attestation requirement. *See id.* ¶¶ 91-112. And any use or disclosure of information that is inconsistent with the Final Rule’s new regulatory standards carries the risk of criminal penalties. *See id.* ¶ 89; 42 U.S.C. § 1320d-6(b). These new “regulatory burden[s] … cause[] injury.” *Tennessee v. EEOC*, 129 F.4th at 458. Having alleged that they are the “direct object” of the Final Rule and would “be spared” from the rule’s mandates if it were declared unlawful, Plaintiff States have pleaded a redressable “injury in fact” establishing standing. *Carmen*, 112 F.4th at 407 (cleaned up).

### 3. HHS’s counterarguments flounder on law and fact alike.

Targeting the complaint, HHS dismisses Plaintiff States’ allegation that the Final Rule impedes state investigations as “conclusory, speculative, and vague” because the complaint does not “explain[] how the Rule is *actually* impeding any investigation.” HHS Br. 10 (emphasis added). Yet HHS then concedes that the complaint details multiple investigations the attestation requirement has hampered—including one in which a healthcare provider refused to comply with a request for information from a state agency that provided an attestation. *Id.* at 10 & n.1 (citing Compl. ¶ 110). In short, the States provide details aplenty—even on HHS’s selective accounting.

Contra HHS (at 10), these allegations do not require “guesswork” about the Final Rule’s impacts. Consider paragraph 107. Tennessee is litigating a consumer protection case against a physician and his fertility clinic. Compl. ¶ 107. But during discovery the State could not “obtain relevant patient data subject to HIPAA’s protections, without the attestation required by the Final Rule, which a state employee must sign under pain of criminal liability.” *Id.* Without the Final Rule, no attestation would be necessary, meaning one less barrier to investigators’ obtaining the discovery they have requested. So it is beside the point whether, for example, state officials could obtain the information “by some other means” or whether they received the information upon providing an attestation, HHS Br. 11, because Congress prohibited any “*limit*” on States’ investigative authorities, *see Purl v. HHS*, No. 2:24-

cv-228, 2024 WL 5202497, at \*6-10 (N.D. Tex. Dec. 22, 2024).<sup>4</sup> And, as Plaintiff States explained, the Final Rule’s vague, broad “terms appear to sweep in any records request relating to the provision of care in a range of areas,” Compl. ¶ 65, making it “foreseeable” this same unlawful limitation will arise in nearly every case, *id.* ¶ 103.<sup>5</sup>

Beyond explaining how the Final Rule imposes barriers to investigations promoting States’ sovereign interest in “safeguard[ing]” their “domain” and their citizens’ “health, comfort and welfare,” *Kentucky v. Biden*, 23 F.4th at 596, the complaint plausibly alleges that overcoming those barriers costs time and money. Plaintiff States’ complaint lays out the complex, high-stakes legal analysis an investigator must undertake each time his signs an attestation. Compl. ¶¶ 79-89, 91-112. It also explains that Plaintiff States’ HIPAA-covered entities must undertake a similar analysis each time they receive a request for information or an attestation. *Id.* ¶¶ 66-78, 113-15. Neither investigators nor HIPAA-covered entities would have to navigate this morass but for the Final Rule, *see id.* ¶¶ 59-66, and Plaintiff States explained that to avoid the Final Rule’s criminally punishable pitfalls, it has been necessary to develop “processing systems” or “overhaul” those systems already in place, *see id.* ¶¶ 99, 111, 115. The time, personnel, and resources required to conduct these compliance measures “produce[] administrative costs.” *Id.* ¶¶ 99, 115. Indeed, these are exactly the administrative costs that HHS itself predicted. *See* 89 Fed. Reg. at 33,054-56 (anticipating costs for, among other things, implementing the new attestation requirement, altering disclosure policies, and training staff). Thus, accepting the complaints’ allegations as true and drawing all reasonable inferences in Plaintiff States’ favor, *Block v. Canepa*, 74 F.4th 400, 408 (6th Cir. 2023), they have adequately alleged compliance costs.

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<sup>4</sup> For “standing purposes,” courts accept the merits of a plaintiff’s claims “as valid.” *Kentucky v. Yellen*, 54 F.4th at 349 n.16 (citation omitted).

<sup>5</sup> Those allegations have been borne out. In the months since the Final Rule has taken hold, state investigators have consistently received requests for attestations, even in matters lacking a “reproductive health care” hook. *See, e.g.*, Zeigler Decl. ¶¶ 8-11; Zeigler Supp. Decl. ¶¶ 8-10.

Plaintiff States need not provide a “precise dollar figure” for those costs. *Rest. L. Ctr. v. U.S. Dep’t of Lab.*, 66 F.4th 593, 600 (5th Cir. 2023). Nor must they allege that the costs are “material[]” or particularly “extra.” HHS Br. 11. After all, “a loss of even a small amount of money” is a concrete injury for purposes of Article III. *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

The cases HHS cites (at 11) do not say otherwise. Unlike Ohio, Plaintiff States’ *complaint* explains that the Final Rule triggers analyses and procedures that impose “financial, logistical, and personnel burdens,” *see* Compl. ¶ 115, and Plaintiff States have backed those allegations with “affidavit[s]” and “other evidence.” *Compare Ohio v. Yellen*, 53 F.4th 983, 994 (6th Cir. 2022). The D.C. Circuit reasonably chose not to over read a single sentence in a party’s reply brief in *Interstate Nat. Gas Association of America v. FERC*, 285 F.3d 18, 46 (D.C. Cir. 2002), but Plaintiff States’ complaint lays out fully the burdens imposed by the Final Rule, *supra* 5-7. And HHS’s reliance on *Kentucky v. EPA*, No. 2:23-cv-7-GFVT, 2023 WL 3326102, at \*3 (E.D. Ky. May 9, 2023), is particularly misplaced given that the Sixth Circuit administratively stayed the district court’s decision in that case *sua sponte* because its standing analysis so missed the mark. Order, ECF No. 9, *Kentucky v. EPA*, Nos. 23-5343/5345 (6th Cir. Apr. 20, 2023); *see* Order, ECF No. 24, *Kentucky v. EPA*, Nos. 23-5343/5345, at 6-7 (6th Cir. May 10, 2023) (finding challengers’ “costs to ensure their compliance” as well as risk of punishment sufficient to show irreparable injury). In so doing, the Sixth Circuit rejected HHS’s suggestion that pleading compliance costs requires exacting detail about steps taken and specific costs incurred. *See* Order, ECF No. 24, *Kentucky v. EPA*, Nos. 23-5343/5345, at 5-6.

Most fundamentally, HHS seeks (at 10-11) to require pleading at a level of granular detail that is simply not required when the plaintiff is “the direct object” of an agency action. *Carmen*, 112 F.4th at 407. Plaintiff States cannot distinguish between prohibited and permissible disclosure of a record without analyzing the underlying HIPAA-protected information or the potential ends of an investigation. *See, e.g.*, 89 Fed. Reg. at 33,004 (disclosure permitted “where there is suspicion of sexual abuse

that could be the basis of permitted reporting,” but not if suspicion “[is] based solely on the fact that a parent seeks reproductive health care...for a child”). And Plaintiff States have plausibly alleged that providing attestations, screening for “reproductive health care,” and questioning a requestor’s motives and purpose “increase[] regulatory burden[s],” which “satisfies the injury-in-fact-requirement.” *Texas v. Becerra*, 577 F. Supp. 3d 527, 555 (N.D. Tex. 2021); *see also Tennessee v. EEOC*, 129 F.4th at 458. It is “unnecessary” to further “consider whether the requirement caused any specific economic harms.” *Tennessee v. EEOC*, 129 F.4th at 458 (describing the Court’s standing decision in *West Virginia v. EPA*). Rather, it is sufficient that Plaintiff States have alleged that the Final Rule mandates “some action[s],” those mandates are unlawful, and this Court can “spare[]” Plaintiff States by setting the rule aside. *Carmen*, 112 F.4th at 407-08 (citations omitted). HHS’s motion to dismiss thus should be denied.

**B. Plaintiff States’ evidence adequately supports standing for entry of relief.**

Since Plaintiff States have put forward evidence that the Final Rule’s new burdens are an on-going problem, they’ve likewise cleared the standing requirement for entry of summary judgment and injunctive relief. Again, HHS’s attempt to sidestep the States’ evidence-backed showing fails.

1. Plaintiff States attached to their motion for summary judgment and preliminary relief fifteen declarations from various state officials detailing the burdens the Final Rule has imposed. They explain that States regularly conduct public-health investigations that require seeking HIPAA-protected information. *See, e.g.*, Groover Decl. ¶¶ 3, 9-11; Zeigler Decl. ¶¶ 3-4; Traxler Decl. ¶¶ 3-6. Before the Final Rule, investigators could propound requests for information on HIPAA-covered entities without considering whether “reproductive health care” was at issue or providing an attestation, and HIPAA-covered entities typically complied with those requests. *See, e.g.*, Zeigler Decl. ¶ 5; Jonhson Decl. ¶¶ 5-9; *see also* Pack Decl. ¶¶ 8-10. Now that HIPAA-covered entities must comply with the Final Rule, they are either denying investigators’ requests for information or demanding the attestation required by the Final Rule, even in cases well outside the heartland of “reproductive health

care.” *See, e.g.*, Groover Decl. ¶¶ 7-8; Targia Decl. ¶ 18 & Attachment A; Joiner Decl. ¶¶ 8-9; Zeigler Decl. ¶¶ 8-11; *see also* Harrelson Decl. ¶¶ 14-16.

HHS (at 12-14) does not deny these new burdens; it just thinks they aren’t that burdensome. But having to clear *any* new hurdle is an Article III injury since “[t]he imposition of a regulatory burden itself causes injury.” *Tennessee v. EEOC*, 129 F.4th at 458. That’s particularly so here, where Congress prohibited any “*limit*” on States’ investigative authorities, *see Purl*, 2024 WL 5202497, at \*6-10.

Regardless, navigating the attestation requirement is not the small task HHS claims. Investigators must sign attestations and use HIPAA-protected information under threat of potential criminal liability. 42 U.S.C. § 1320d-6(b); *see also* 89 Fed. Reg. at 33,030 (“adding another new required element[:] a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses [information] relating to another individual … may be subject to criminal liability”). Thus, investigative agencies have had to consider their processes for requesting information and providing attestations. *See, e.g.*, Azar Decl. ¶¶ 12-15; Stover Decl. ¶¶ 7-11; Karrasch Decl. ¶¶ 10-12; *see also* Davies Decl. ¶¶ 7-10. For specific cases, an attestation demand requires investigators to consult internally to confirm whether the information sought could touch on “reproductive health care” data. *See, e.g.*, Menefee Decl. ¶¶ 7-14; Kreutz Decl. ¶¶ 16-17; *see also* Harrelson Decl. ¶¶ 14-17; Zeigler Supp. Decl. ¶¶ 11-13. This can include seeking legal counsel and carefully re-evaluating the information sought, particularly because these requests often come early in an investigation, before the full extent of potential wrongdoing is known. *See, e.g.*, Menefee Decl. ¶¶ 8-9; Dietz Decl. ¶ 18; Zeigler Decl. ¶ 12; Kreutz Decl. ¶¶ 16-21; *see also* McKnight Decl. ¶¶ 14-18.

Conducting these evaluations takes time, resources, and personnel, particularly because the Final Rule’s vague, broad standards create uncertainty around its application and the risks of criminal liability that come with that. *See, e.g.*, Traxler Decl. ¶¶ 18-21; *see also* Davies Decl. ¶¶ 8-9. Sometimes the process may end in a decision not to provide an attestation. *See, e.g.*, Zeigler Decl. ¶¶ 8-12. At

other times investigators may provide an attestation but the HIPAA-covered nonetheless denies the request for information, which the Final Rule allows. Even when things go smoothly—*i.e.*, when investigators provide an attestation and the covered entity provides the requested information—investigators were subjected to additional, front-end work unlawfully required by the Final Rule. In each instance, the Final Rule’s new regulatory burdens—which have slowed or stymied many public health investigations promoting Plaintiff States’ sovereign interests, *see, e.g.*, Groover Decl. ¶¶ 7-9; Zeigler Decl. ¶¶ 8-11; Johnson Decl. ¶¶ 9-15; Dietz Decl. ¶¶ 18-22; *see also* Davies Decl. ¶¶ 8-10; Hardin Decl. ¶¶ 9-11—“cause[] injury” for standing purposes. *Tennessee v. EEOC*, 129 F.4th at 458.

2. None of HHS’s remaining standing counters is convincing. HHS’s curious claim that “the record is *devoid of any*” evidence, HHS Br. 12 (emphasis added), misses the fifteen-declaration elephant in the room. Upon later confronting the declarations, HHS claims they are insufficient because they demonstrate only self-inflicted harm rather than harm traceable to the Final Rule. HHS Br. 12-13 (citing *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416 (2013)). Not so. Plaintiff States’ declarations lay out repeatedly how the Final Rule is adding new, unlawful barriers to investigators’ obtaining vital information. Whether investigators might successfully overcome the Final Rule’s burdens in any one case does not disprove standing; Plaintiff States’ point is that *no* burdens the Final Rule imposes are lawful, and that satisfying any such burden requires time, energy, and resources that’s typically the stuff of APA standing. *See Tennessee v. EEOC*, 129 F.4th at 458. Anyway, the declarations’ detailing of investigative efforts *does* provide the concrete evidence of “compliance costs” that HHS claims (at 14) is lacking. For example, investigators have been denied information without an attestation, *see, e.g.*, Zeigler Decl. ¶ 11, which has required internal consultation and discussions with legal counsel, *see, e.g.*, Johnson Decl. ¶ 11; Kreutz Decl. ¶ 17; *see also* McKnight ¶¶ 11-14, as well as dialogue with hospitals and other covered entities, *see, e.g.*, Traxler Decl. ¶ 19; *see also* Zeigler Supp. Decl. ¶¶ 11-13, and investigators have had to consider whether and how to seek recourse against covered entities that

deny requests, *see, e.g.*, Spahr Decl. ¶¶ 16, 18; Davies Decl. ¶ 10. Plus, covered entities incur parallel costs when navigating similar factors before disclosing information. *See, e.g.*, Hardin Decl. ¶¶ 8-10.

Nor should these costs catch HHS off-guard. They are akin to the costs HHS's Final Rule predicted for *all* covered entities. *See* 89 Fed. Reg. at 33,054-56. Having spotted *all* regulated entities increased costs in the Final Rule, HHS cannot now credibly suggest (at 14) that the Final Rule lacks a “*particularized*” effect on Plaintiff States. *Cf. SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943).

Finally, HHS notes (at 12) that some Plaintiff States did not attach declarations to the motion for relief. For a few reasons, that is no problem here. First, as explained, *supra* 3-6, States' standing as directly regulated parties is both “self-evident,” *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 508, and posited in the body of the Final Rule, *see* 89 Fed. Reg. at 33,054-56. Second, at least one Plaintiff State has demonstrated standing for the reasons above, and “only one plaintiff needs to have standing in order for the suit to move forward.” *Parsons v. U.S. Dep't of Just.*, 801 F.3d 701, 710 (6th Cir. 2015). Plaintiff States seek the APA's “default” vacatur remedy, *Kentucky v. EPA*, 123 F.4th at 472-73, “which is not party-restricted,” *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024); *cf. Griffin v. HM Florida-ORL*, 144 S. Ct. 1, 1, n.1 (2023) (Kavanaugh, J., concurring in stay denial) (explaining APA remedies). Third, to the extent equitable relief hinges on party-specific evidence, Plaintiff States submit additional declarations in support of their requested relief. *Supra* 3 n.2.

## II. The Final Rule is unlawful.

As Plaintiff States previously explained, the Final Rule's mandates exceed HHS's statutory authority under HIPAA. States' Br. 12-20. And the Final Rule's regulatory regime is not the product of reasoned decision-making. *Id.* at 20-22. HHS has forfeited those arguments by declining to

respond to them. *See Adkins*, 105 F.4th at 854.<sup>6</sup> Thus, the Court should hold the Final Rule “unlawful” and “set [it] aside.” *See* 5 U.S.C. § 706(2)(A), (C).<sup>7</sup>

### **III. This Court can and should vacate the Final Rule.**

The APA’s instruction that reviewing courts “shall … hold unlawful and set aside” any agency action that is “arbitrary, capricious,” or “in excess of statutory jurisdiction[ or] authority,” 5 U.S.C. § 706(a)(A), (C), authorizes vacatur of the unlawful agency action. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Corner Post*, 603 U.S. at 829 (Kavanaugh, J., concurring) (“[T]he APA authorizes vacatur of unlawful agency actions, including agency rules.”). In fact, vacatur is “the default” remedy, and narrower alternative remedies are “rare.” *Kentucky v. EPA*, 123 F.4th at 473. As Plaintiff States explained previously, States’ Br. 23, because this straightforward APA challenge is not one of those “rare” cases, the APA’s “normal” vacatur remedy is warranted. *See Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 51-52 (D.D.C. 2020) (K.B. Jackson, J.). HHS’s arguments to the contrary are unavailing. So is its attempt to salvage scraps of a rule promulgated explicitly to guard “reproductive health care” information, 89 Fed. Reg. at 32,978, after the provisions achieving that purpose are stripped out.

*First*, HHS responds (at 15-16) by slaying a strawman. Plaintiff States never suggested that vacatur is “*required*.” Rather, they explained that vacatur is “the default” APA remedy in this circuit, *Kentucky v. EPA*, 123 F.4th at 472-73, and the Final Rule’s many “legal flaws warrant” that normal

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<sup>6</sup> Two localities and a nonprofit group moved to intervene to defend the Final Rule. *See* Mot. to Intervene, Dkt. #31 (Feb. 10, 2025). Their intervention motion remains pending. Under this Court’s scheduling order, *see* Dkt. #71, Plaintiff States will submit a supplemental brief replying to the Proposed Intervenors’ opposition to summary judgment no later than 14 days after an order granting intervention, if any.

<sup>7</sup> Courts regularly decide APA cases without the administrative record when, as here, it “is not necessary for [the court’s] decision.” *See Connecticut v. U.S. Dep’t of Interior*, 344 F. Supp. 3d 279, 294 (D.D.C. 2018). In any event, HHS already filed the administrative record related to the Final Rule in *Purl v. HHS*, No. 2:24-cv-228 (N.D. Tex.). This “Court may take judicial notice of public records and government documents available from reliable sources on the internet.” *Roane Cnty. v. Jacobs Eng’g Grp., Inc.*, No. 3:19-CV-206-TAV-HBG, 2020 WL 2025613, at \*3 (E.D. Tenn. Apr. 27, 2020) (citations omitted). Or HHS could be ordered to re-file that same record here in short order. But a current lack of administrative record is no reason to delay resolving this case.

remedy here. States' Br. 23. Indeed, vacatur is "the *ordinary result*" when a reviewing court determines that agency regulations are unlawful. *Corner Post*, 603 U.S. at 831 (Kavanaugh, J., concurring) (emphasis added) (citation omitted). The D.C. Circuit—"where much litigation concerning federal agencies takes place," *see Sierra Club v. EPA*, 60 F.4th 1008, 1022 (6th Cir. 2023)—applies this same default. *See, e.g., Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) ("[V]acatur is the normal remedy[.]"). As do the First, Third, Fifth, Ninth, Tenth, and Eleventh Circuits.<sup>8</sup>

HHS must explain why this Court should deviate from this well-established norm; it is not enough to say (at 16) that courts *can* do so. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. But HHS fails to justify its request for narrower relief. Maybe courts have declined to order universal vacatur when a plaintiff does not seek it or in light of certain equitable considerations. *See* HHS Br. 16 (citing, *e.g., Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 521-27 & *Ohio Env't Council v. U.S. Forest Serv.*, 2023 WL 6370383, at \*2-5 (S.D. Ohio Aug. 3, 2023)). But that says nothing about whether this Court should deny Plaintiff States "the default" relief that they do seek when HHS "has failed to establish that the equities justify" something else. *Kentucky v. EPA*, 123 F.4th at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. That's especially true given that the cases HHS cites to support its request for alternative relief treat vacatur as the "[n]ormal" APA remedy. *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d at 521; *see also GBX Assocs., LLC v. United States*, 2022

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<sup>8</sup> *See, e.g., Martinez v. Bondi*, No. 24-1057, 2025 WL 855018, at \*9 (1st Cir. Mar. 19, 2025) ("Under the so-called 'ordinary remand rule,' an error of this kind would thus typically result in vacatur of the agency's decision[.]") (citation omitted); *Comite' De Apoyo A Los Trabajadores Agricolos v. Perez*, 774 F.3d 173, 191 (3rd Cir. 2014) ("Ordinarily, reviewing courts have applied [APA § 706(2)] by vacating invalid agency action and remanding the matter to the agency for further review."); *Rest. L. Ctr. v. U.S. Dep't of Labor*, 120 F.4th 163, 177 (5th Cir. 2024) ("[O]ur court's 'default rule is that vacatur is the appropriate remedy.'") (citation omitted); *E. Bay Sanctuary Covenant v. Garland*, 994 F.3d 962, 987 (9th Cir. 2020) ("Because the Rule is 'not in accordance' with [statutory authority], our obligation as a reviewing court is to vacate the unlawful agency action."); *High Country Conservation Advoc. v. U.S. Forest Serv.*, 951 F.3d 1217, 1228 (10th Cir. 2020) ("The typical remedy for an [unlawful agency action] is remand to the district court with instructions to vacate the agency action."); *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1290 (11th Cir. 2015) ("[V]acatur ... is the ordinary APA remedy[.]") (citation omitted).

WL 16923886, at \*15-18 (N.D. Ohio Nov. 14, 2022) (assuming “that federal courts have the authority to order universal vacatur” and justifying its decision to enter less-than-full vacatur); *Ohio Env’t Council*, 2023 WL 6370383, at \*2 (calling vacatur “[t]he standard remedy for violations of the APA”).

*Second*, HHS suggests (at 16 & n.5) that vacatur is *not allowed* because it “contradict[s] constitutional and equitable limitations on this Court’s remedial authority.” But that stance “disregards a lot of history and a lot of law.” *Corner Post*, 603 U.S. at 827 (Kavanaugh, J., concurring) (quoting M. Sohoni, *The Past and Future of Universal Vacatur*, 133 Yale L. J. 2304, 2310-11 (2024)); *cf. supra* 14 n.8 (collecting cases). “Over the decades, [the Supreme] Court has affirmed countless decisions that vacated agency actions, including agency rules.” *Corner Post*, 603 U.S. at 830 (Kavanaugh, J., concurring) (collecting cases). That includes cases in which a court may have been able to craft party-specific remedies. *See, e.g.*, *Bd. of Governors of Fed. Rsrv. Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 364-65 (1986); *see also, e.g.*, *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143-48 (6th Cir. 2022). None of the cases HHS cites (at 16-17) requires the contrary. Indeed, “[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Harmon v. Thornburgh*, 878 F.2d 484, 495 n. 21 (D.C. Cir. 1989) (emphasis added).

*Third*, HHS misdirects to other pending actions. Contra HHS (at 17), though, an order from this Court vacating the Final Rule need not preempt review of other parallel challenges that are pending in other courts. As the Department of Justice recently explained to a district court in Texas, a case challenging a rule “remains a live controversy” even if another district court “enter[s] judgment vacating” that same rule until that “judgment is affirmed on appeal and no further appellate review is available” or “the deadline to appeal passes without” a party filing a notice of appeal. Joint Status Report, Dkt. #85, *Carroll Indep. Sch. Dist. v. U.S. Dep’t of Educ.*, No. 4:24-cv-461-O (N.D. Tex. Feb. 17, 2025). Therefore, other plaintiffs’ pending challenges can continue even after a vacatur order from this Court,

meaning the “best ideas” about whether HHS’s Final Rule is lawful can “percolate to the top.” *Cf. Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring).

*Fourth*, this is not a case in which equity favors narrower relief, like remand without vacatur. *Kentucky v. EPA*, 123 F.4th at 473. When considering whether to stray from the APA’s “default” remedy, courts consider “how serious of an error the agency made” and “how disruptive … vacatur would be.” *Id.* at 472-73; *see also Allina Health Servs.*, 746 F.3d at 1110. It is “rare” that these factors militate against the default vacatur remedy, *Kentucky v. EPA*, 123 F.4th at 472-73, and it is not even clear whether such relief is available in the Sixth Circuit if an agency action is unlawful, *see id.* at 478-79 (Murphy, J., concurring). In the “rare” case the Sixth Circuit “has remanded to an agency without vacating its action” the court “did not find the action unlawful and instead remanded for additional proceedings at the agency’s request.” *Id.* at 472 (citing *Sierra Club*, 60 F.4th at 1021-23).

That is not this case. HHS’s “exceeding [its] statutory authority is a serious defect.” *Ins. Mktg. Coal. Ltd. v. FCC*, 127 F.4th 303, 317 (11th Cir. 2025). Indeed, because federal agencies’ “power to act … is authoritatively prescribed by Congress,” *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013), the Final Rule is “a substantively illegal action,” and narrowed relief is not appropriate to address such “‘fundamental’ error[s].” *Kentucky v. EPA*, 123 F.4th at 472. On that basis alone, this Court should not “let the action stand.” *Id.* And because HHS erected a scheme “so implausible that it could not be … the product of agency expertise,” *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), it would be illogical to preserve the Final Rule while the agency takes a futile second go at justifying it. *See Louisville Gas & Elec. Co. v. FERC*, 988 F.3d 841, 843, 848-49, 851 (6th Cir. 2021) (vacating agency action upon finding agency acted arbitrarily and capriciously).

Nor has HHS demonstrated that vacatur would be particularly disruptive. Vacatur would not “upend years” of “reliance on the agency’s action.” *Kentucky v. EPA*, 123 F.4th at 473. So “[t]his is not a case in which the ‘egg has been scrambled,’ and it is too late to reverse course.” *Allina Health*

*Servs.*, 746 F.3d at 1110 (citation omitted). If anything, narrower, party-specific relief could cause more disruption or confusion than vacatur, as regulated parties would be forced into navigating dueling regulatory regimes depending on the identity of the entity seeking or disclosing information. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165-66 (2010) (finding “no recourse to … an injunction” is “warranted” if vacatur is viable). This could “add to the confusion” among affected parties and potentially put regulated officials in a “position of trying to communicate” multiple, conflicting instructions over the span of the case. *Ohio State Conf. of NAACP v. Husted*, 769 F.3d 385, 389-90 (6th Cir. 2014). On the other hand, vacatur would assure regulated parties that the familiar, long-standing Privacy Rule again governs. While Plaintiff States are sympathetic to the costs that covered entities have sunk into modifying their “policies or practices” to comply with the rule, *see supra* 7, 9-11 (explaining Plaintiff States bear those same costs), HHS is wrong to suggest (at 18) that any covered entity has a legitimate interest in “continu[ing]” to “operat[e] under” a rule that unlawfully impedes States’ sovereign authority. As the Sixth Circuit has noted in similar contexts, “the public’s true interest lies in the correct application of the law.” *Tennessee v. U.S. Dep’t of Educ.*, 104 F.4th at 614 (cleaned up).

*Fifth*, the Final Rule’s severability provision does not salvage the scraps left over after excising the unlawful provisions regarding “reproductive health care” information. HHS was explicit about its motivation for promulgating the Final Rule: “In order to continue to protect privacy in a manner that promotes trust between individuals and health care providers and advances access to, and improves the quality of, health care,” after *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215 (2022), HHS “determined that the Privacy Rule must be modified to limit the circumstances in which provisions of the Privacy Rule permit the use or disclosure of an individual’s [information] about reproductive health care[.]” 89 Fed. Reg. at 32,978. So along those lines, each regulatory change made in the Final Rule either creates the new “reproductive health care” regime or conforms the Privacy Rule to its new standard. *See, e.g.*, 45 C.F.R. § 164.520(b)(ii)(F)-(H) (amended requirement to provide “[n]otice of

privacy practices” to ensure coverage of “reproductive health care” information).

HHS does not explain how any of the Final Rule’s amendments to the Privacy Rule concern something else or could be partially implemented. Nor has HHS “identified any evidence that it contemplated” “enforcement of the Rule without *any* of the core provisions” Plaintiff States have challenged. *Tennessee v. Cardona*, 2024 WL 3453880, at \*4. To the contrary, given the Final Rule’s post-*Dobbs* justification, there is “substantial doubt” HHS would have promulgated the Final Rule absent the challenged limitations. *Mayor of Baltimore v. Azar*, 973 F.3d 258, 292-93 (4th Cir. 2020) (citation omitted). The severability clause thus has “little impact on the Court’s analysis because the” illegal portions of the Final Rule “permeate[]” its remaining bits. *Tennessee v. Cardona*, 737 F. Supp. 3d 510, 570 (E.D. Ky. 2024). On top of that, the justification for the Final Rule rests on arbitrary-and-capricious reasoning, “resulting in a rule that is invalid in its entirety.” *Id.* at 570. In short, given the Final Rule’s widespread legal defects, the Final Rule’s severability clause is not the get-out-of-jail-free card HHS claims. *See Ohio v. EPA*, 603 U.S. 279, 294-97 (2024). The Court should apply the default remedy and vacate the Final Rule in its entirety. *Kentucky v. EPA*, 123 F.4th at 472-73.

#### **IV. At a minimum, preliminary relief is warranted.**

Even if this Court declines entry of final judgment, Plaintiff States have demonstrated entitlement to the requested preliminary relief. Contra HHS (at 14-15), the same harms detailed in Plaintiff States’ complaint and declarations establish that the Final Rule inflicts irreparable harm. The new barriers for investigators to obtain HIPAA-protected information are slowing or halting public health investigations, damaging Plaintiff States’ sovereign interest in “safeguard[ing] ‘[their] domain’ and [their citizens’] ‘health, comfort and welfare.’” *Kentucky v. Biden*, 23 F.4th at 596 (citations omitted). Such sovereign harms are irreparable injuries. *See Tennessee v. U.S. Dep’t of Educ.*, 104 F.4th at 591-95. As are the compliance costs Plaintiff States must expend under the Final Rule. *See Kentucky v. Biden*, 57 F.4th at 555-56. Because the federal government enjoys sovereign immunity, Plaintiff States cannot

recover the sunk costs of complying with the rule. *Id.*

Nor can HHS (at 15) lean on Plaintiff States’ alleged “seven-month delay.” Though the Final Rule became effective in June 2024, compliance was not required until late December 2024. 89 Fed. Reg. at 32,976. Plaintiff States sued within weeks of the costs and impacts of compliance materializing—enabling an evidentiary showing that details their ongoing harms. Elsewhere, the federal government has knocked States’ pre-effective-date suits as too *early* to support preliminary relief.<sup>9</sup> Having sued now when directly subject to Final-Rule compliance, Plaintiff States’ case for injunctive relief should not suffer under HHS’s heads-I-win, tails-you-lose approach to relief.

The requested preliminary relief is appropriately tailored. The APA allows the court to “postpone the effective date of an agency action.” 5 U.S.C. § 705; *see* Compl. at 32 (requesting “a stay ... that preserves the States’ rights against the Final Rule pending review”). Such relief need not be “party-restricted.” *Career Colls. & Sch. of Tex.*, 98 F.4th at 255. This result tracks the difference between the APA context—where vacatur of a rule “for everyone” is the normal remedy, *Kiakombua*, 498 F. Supp. 3d at 52 (citation omitted)—and non-APA cases involving requests for equitable relief that flow to particular parties, *cf. e.g.*, *Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 928-34 (2024) (Kavanaugh, J., concurring). And courts “routinely stay already-effective agency action under Section 705.” *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022); *see also, e.g.*, *Airlines for Am. v. U.S. Dep’t of Trans.*, 110 F.4th 672, 677 (5th Cir. 2024) (stay granted July 29, 2024; 89 Fed. Reg. 34,620 effective July 1, 2024); *Kansas v. United States*, No. 1:24-cv-150-DMT, 2024 WL 5220178, at \*9 (D.N.D. Dec. 9, 2024) (89 Fed. Reg. 39,392 effective Nov. 1, 2024); *Int’l Fresh Produce Ass’n v. U.S. Dep’t of Labor*, No. 1:24-cv-309-

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<sup>9</sup> *See, e.g.*, Def.’s Mem. in Opp’n to Pltfs.’ Mot. for a § 705 Stay & Prelim Inj. 21, Dkt. #34, *Tennessee v. EEOC*, No. 2:24-cv-84 (E.D. Ark. May 17, 2024) (arguing pre-enforcement challenge was unripe and court should await “concrete setting” of challenged rule’s application); Defs.’ Opp’n to Pltfs.’ Mot. for a § 705 Stay & Prelim Inj. 22, *Tennessee v. Cardona*, No. 2:24-cv-72, Dkt. #73 (E.D. Ky. May 24, 2024) (arguing States lack “imminent” injury and suggesting they wait to challenge enforcement “once the Rule goes into effect”).

HSO, 2024 WL 4886058, at \*12 (S.D. Miss. Nov. 25, 2024) (89 Fed. Reg. 33,898 effective June 28, 2024); *Gomez v. Trump*, 485 F. Supp. 3d 145, 205 (D.D.C. 2020) (stay granted Sep. 4, 2020; 85 Fed. Reg. 23,441 effective Apr. 23, 2020; 85 Fed. Reg. 38,263 effective June 24, 2020)

Even if this Court favors the more traditional preliminary injunction route, every State plaintiff is entitled to that relief. HHS repeats (at 20) that a few States did not initially provide harm declarations. But as already explained, it is “self-evident” and conceded by the Final Rule itself that it irreparably harms those States. *See Tennessee v. U.S. Dep’t of Educ.*, 615 F. Supp. 3d 807, 842 (E.D. Tenn. 2022) (granting injunctive relief to all plaintiff States, including States that did not provide a harm declaration), *aff’d* by 104 F.4th at 613. And in any event, more States have now submitted declarations. *Supra* 3 n.2. Nor would it be sufficient to enjoin only the attestation requirement, as HHS suggests (at 20-21). The Final Rule’s hindering state investigators demonstrates the significant harms that flow from the Final Rule’s regime, but the costs and burdens placed on Plaintiff States’ covered entities are equally harmful and unlawful, *see* Compl. ¶¶ 113-15; *Purl*, 2024 WL 5202497, at \*4-10. Any time a State, as a HIPAA-covered entity, receives a request for information it must devote “resources to comply with the Final Rule’s byzantine procedural burdens.” States’ Br. 24; *see also* Hardin Decl. ¶¶ 8-10. There is no “application of the Rule[s]” limitations on the use or disclosure of “reproductive health care” information Plaintiff States has not alleged is “unlawful.” HHS Br. 21.

## CONCLUSION

This Court should grant summary judgment to Plaintiff States and set aside the Final Rule as unlawful. At a minimum, preliminary relief against the Final Rule pending the case’s resolution is warranted.

Date: April 3, 2025

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served via the Court's electronic filing system on this 3rd day of April, 2025 to all counsel of record.

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